



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,063	09/10/2003	Mitchell P. Fink	UPITT-008XX	3827

207 7590 03/25/2005

WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP
TEN POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER

HENRY, MICHAEL C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,063

Applicant(s)

FINK ET AL.

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 9-13 is/are pending in the application.
4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6 and 8 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 10 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 12/02/04.

The amendment filed 12/02/04 affects the application, 10/659,063 as follows:

Claims 1 and 8 have been amended. Claim 7 has been canceled. Claims 9-13 are withdrawn. Claims 1-6 and 8, the invention of Group I are prosecuted by the examiner.

Applicant responds to the rejection under 35 USC 103 by amending claim 1.

The responsive to applicants' arguments is contained herein below.

Claims 1-6, 8, 9-13 are pending in application

Applicant's election without traverse of the invention of Group I in the reply filed on 12/02/04 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The specification, while being enabling for the treatment of inflammatory condition, does not reasonably provide enablement for the prophylaxis (or prevention) of inflammatory condition. First, in claim 1, the applicant claims "A method for prophylaxis or treatment of an inflammatory condition, said method comprising the steps of: providing a patient having an inflammatory condition; and administering to said patient

Art Unit: 1623

a therapeutically effective amount of a composition comprising cyclic adenosine diphosphate ribose (cADPR), or a functional analogue or derivative thereof, in a form that is accessible to a receptor molecule, conveyed in a pharmaceutically acceptable carrier vehicle, wherein said composition reduces the degree of said inflammatory condition in said patient.” The prophylaxis (or prevention) of inflammatory conditions is not enabled since the said inflammatory conditions does not have a single recognized cause. More specifically, inflammatory conditions encompass a vast number of ailments or disorders. These conditions include arthritis, pulmonary diseases, psoriasis, colitis, multiple sclerosis, systematic lupus erythematosus, juvenile diabetes, atherosclerosis, hypothyroidism, tonsillitis, pharyngitis, otitis media, inflammatory bowel disease, bronchitis, inflammatory diseases of the central nervous system such as algal disorders, bacterial disorders, idiopathic inflammatory disorders, parasitic encephalomyelitis and viral disorders. In fact, the aforementioned inflammatory conditions, are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyles choices such as the diet and maintenance of bodily healthiness. These are only a few of the factors that promote these conditions in people. Furthermore, the specification does not reasonably provide enablement for the prevention of said condition in a patient (which includes a human). The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art, and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed methods with a reasonable expectation of success. Therefore, the prophylaxis (prevention) of the said inflammatory condition by one method and one compound is not enabled by the instant disclosure. It should be noted that, the prevention and cause(s) of inflammatory disease such as

Art Unit: 1623

crohn's disease (as claimed by applicant) is not known (for example, see, <http://www.healthcentral.com/mhc/top/000249.cfm>, article from the General Health encyclopedia). Dependent claims 2-6 and 8, are also not enabled for the prophylaxis (prevention) of inflammatory conditions in a patient because of the above stated reasons.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "a functional analogue or derivative" render the claims indefinite. More specifically, in the absence of the specific analogue and derivative to the chemical core claimed (CCC) or distinct language to describe the structural modifications or the chemical names of the analogues of this invention, the identity of said analogues would be difficult to describe and the metes and bounds of said analogues that applicant regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims. Therefore, the identity of this composition component is indefinite. In addition, it is unclear what functions (and how many) must said analogue be capable of performing to be considered a functional analogue.

The terms "phosphorothioate analogues", "N3'-P5' phosphoroamidate analogues" and "analogues with conformationally locked sugar rings" renders the claims indefinite. More specifically, in the absence of the specific analogues to the chemical core claimed (CCC) or distinct language to describe the structural modifications or the chemical names of the analogues

Art Unit: 1623

of this invention, the identity of said analogues would be difficult to describe and the metes and bounds of said analogues that applicant regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Therefore, the identity of this composition component is indefinite. The examiner has found claims 1-6 and 8 to be free of the prior art.

Response to Amendment

Applicant's arguments with respect to the indefiniteness rejection of claim 1 have been considered but are not found convincing.

The applicant argues that the description of specific analogues can be determined by looking at specifically cited reference. However, the identity and the metes and bounds of said analogues that applicant regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims nor by the cited references of the specification.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1623

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

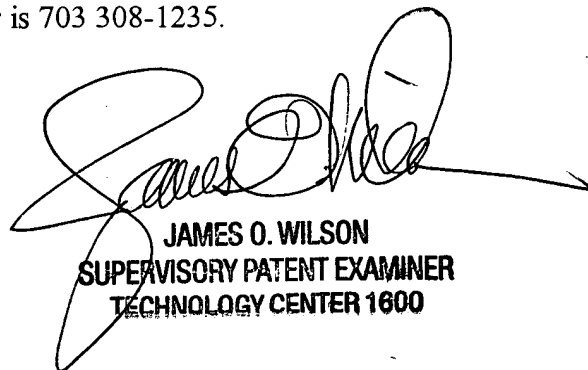
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

March 15, 2005.



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600